

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 9 of 16

Attorney's Docket No.: 10527-522001 / 03-257

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### REMARKS

The Office Action mailed April 7, 2006, rejected all pending and not withdrawn claims 1-25. Claims 26-40 were previously withdrawn as not elected by Applicants in response to a previous restriction requirement. Claims 1 and 18 have been amended above. Accordingly, claims 1-25 remain pending and not withdrawn. Applicants respectfully request reconsideration of these claims in view of the amendments above and the following remarks.

Applicants also note that a Supplemental Information Disclosure Statement (IDS) was filed on July 14, 2006, after mailing of the last Action, and request consideration of the references cited in this Supplemental IDS. For the Examiner's convenience, a copy of the PTO-1449 form filed July 14, 2006 is attached hereto. In addition, copies of the listed references can be resubmitted upon request.

#### **Claim Rejections – 35 U.S.C. § 102**

##### U.S. Patent 6,295,990 to Lewis et al.

The Office Action issued a new rejection of independent claim 1, as well as dependent claims 2, 5, 7 and 11-13 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,295,990 to Lewis et al. (Lewis). While not conceding the merits of the rejection, Applicants have above amended claim 1 to recite further distinctions of the claimed subject matter from Lewis. The amendments add no new matter; support for the amendments appears in Applicants' specification as filed, for example, in Figures 3 and 6 and accompanying discussion at page 9, line 9 to page 11, line 21, and page 14, line 6, to page 15, line 1. Applicants submit that claim 1, as amended, defines subject matter that is patentable over Lewis, as do the rejected dependent claims.

Applicants' claim 1, as amended, is directed to a method of cooling a target tissue region inside a body. The method includes providing non-oxygenated fluid cooled below normal body temperature and oxygenated blood at a normal body temperature to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target temperature range that is one to nine degrees Celsius below normal body temperature. The oxygenated blood is provided so that

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 10 of 16

Attorney's Docket No.: 10527-522001 / 03-257

any continuous period of time during which the tissue region is deprived of oxygenated blood while the non-oxygenated fluid is being provided continues less than two minutes.

Lewis discloses methods that comprise penetrating a perfusion conduit through a blockage of a blood vessel, and subsequently pumping an oxygenated medium through the conduit at a rate or pressure sufficient to relieve ischemia downstream from the blockage. (Col. 3, lines 41-45.) Lewis discloses that the oxygenated medium is preferably blood taken from the patient being treated. (Col. 3, lines 45-46.) In Figure 15 referenced by the Examiner, Lewis discloses a perfusion catheter 600 that has a perfusion conduit 602 and an inflatable balloon 606. (Col. 18, lines 31-35.) The catheter 600 in Figure 15 is shown extending through a partial blockage in a vessel, and the balloon 606 is shown inflated and entirely blocking blood flow through the vessel.

Lewis does not disclose the method set forth in Applicants' claim 1. For example, Lewis does not disclose, as required by Applicants' claim 1, a method in which non-oxygenated fluid (cooled below normal body temperature) is used to provide the cooling of a target tissue region. Rather, Lewis discloses a perfusion method in which an oxygenated medium is used. Further, Lewis does not disclose a method in which the non-oxygenated fluid and oxygenated blood (at normal body temperature) are provided to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target temperature range that is one to nine degrees Celsius below normal body temperature. In addition, Lewis does not disclose, as required by Applicants' claim 1, a method in which the oxygenated blood is provided so that any continuous period of time during which the tissue region is deprived of oxygenated blood while the non-oxygenated fluid is being provided continues less than two minutes.

Lewis also does not render Applicants' claim 1 subject matter obvious. Applicants' method uses a non-oxygenated cooled fluid, and uses techniques that ensure a target tissue region is not deprived of oxygen for too long of a period, despite the use of a non-oxygenated fluid to provide for the cooling. As such, Applicants' method is entirely different from what is disclosed in Lewis, and therefore cannot be said to be made obvious by Lewis.

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 11 of 16

Attorney's Docket No.: 10527-522001 / 03-257

U.S. Patent Publication No. 2004/0167467 A1 to Harrison

The Office Action maintained the previous rejection of independent claims 1 and 18, as well as dependent claims 2-7, 11-13, 19-20, and 24-25 under 35 U.S.C. § 102(e) as being anticipated by Harrison et al. U.S. Patent Publication No. 2004/0167467 A1 (Harrison). Independent claim 1 has been amended, as discussed above, and independent claim 18 has also been amended. The amendment of claim 18 adds no new matter; support for the amendment appears in Applicants' specification as filed, for example, in Figure 6 and accompanying discussion at page 14, line 6, to page 15, line 16. Applicants submit that independent claims 1 and 18, as amended, each define subject matter that is at least novel in view of Harrison, and do the rejected dependent claims.

While Applicants distinguish their claims from Harrison, Applicants reserve the right to remove Harrison as a reference under Section 102(e) should that become necessary (for example, by providing a declaration under 37 CFR 1.131). In other words, the fact that Applicants have distinguished their claims from Harrison should not be taken as an admission that Harrison is properly considered prior art under any subsection of 35 U.S.C. 102, including 102(e). In addition and as the Examiner has acknowledged, because at the time of the present invention, both the present invention and the Harrison reference were subject to be assigned to the same assignee, Scimed Life Systems, Inc., 35 U.S.C. 103(c) provides that Harrison cannot preclude the patentability of the present claim 1 as obvious under 35 U.S.C. 103(a).

Harrison discloses devices and methods to deliver cooled fluid to an internal site in the body. (Abstract). Harrison discloses a method of treating a tissue region by inserting a balloon catheter into a coronary vein that provides access to the tissue region and inflating the balloon to occlude the coronary vein; cooled fluid is delivered from the balloon catheter and distal to the balloon. (Abstract). In particular, Harrison discloses, as cited in the Office Action in rejecting claim 1, that "a balloon 24 on the shaft 22 may be inflated to provide a seal between the catheter's distal end 34 and, for example, a coronary ostium," that "cooled fluid can be supplied to the ischemic tissue region via the coronary artery," and "[t]he seal prevents cooled fluid

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 12 of 16

Attorney's Docket No.: 10527-522001 / 03-257

delivered to the ischemic tissue region from escaping the coronary artery and entering the aorta, and at the same time, prevents warm blood in the aorta from entering the coronary artery . . . .” (Page 2, paragraph 0032.) Harrison also discloses an implementation where “cooled fluid delivered by a dilation catheter 302 is a saline solution 320,” and implementations where “the saline solution 320 could be replaced with blood, a blood substitute, or a mixture of both.” (Page 6, paragraph 0063.)

#### Claims 1-13

Harrison does not disclose all of the limitations of Applicants' independent claim 1, as amended. For example, Harrison does not disclose, as required by claim 1 as amended, a method in which the non-oxygenated fluid and oxygenated blood (at normal body temperature) are provided to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target temperature range that is one to nine degrees Celsius below normal body temperature. In addition, Harrison does not disclose, as required by Applicants' claim 1 as amended, a method in which the oxygenated blood is provided so that any continuous period of time during which the tissue region is deprived of oxygenated blood while the non-oxygenated fluid is being provided continues less than two minutes.

Harrison's disclosure at page 2, paragraph 0032, upon which the Examiner relies, does not disclose this aspect of Applicants' claim 1. First, the primary tissue cooling effect in Harrison is achieved by supplying only cooled fluid (whether it be cooled non-oxygenated saline or cooled oxygenated blood) while a catheter is occluding normal blood flow. As such, this aspect of Harrison does not involve providing cooled non-oxygenated fluid and normal-temperature oxygenated blood to the target tissue region. In addition, while it is true that in Harrison cooled non-oxygenated fluid and normal-temperature blood may be provided to a tissue region when a seal between a catheter's balloon and the blood vessel is removed, the cooled non-oxygenated fluid and normal-temperature oxygenated blood are not provided “in proportions to cool the tissue region and maintain, for an extended period of time greater than two minutes, the

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 13 of 16

Attorney's Docket No.: 10527-522001 / 03-257

temperature of the tissue region within a target temperature range that is one to nine degrees Celsius below normal body temperature," as claim 1 requires.

Applicants note the Examiner's statement that the disclosure on page 6, paragraph 0063 of Harrison, was cited to support the anticipation of claim 18 and not claim 1.

As discussed previously and as the Examiner has acknowledged, Harrison cannot preclude the patentability of claim 1 as obvious, because at the time of the invention both the present invention and Harrison were subject to assignment to the same assignee. 35 U.S.C. § 103(c).

Accordingly, independent claim 1 is patentable in view of Harrison. As such, Applicants ask that the Examiner remove his rejection of independent claim 1, as well as dependent claims 2-7 and 11-13.

#### Claims 18-25

Independent claim 18, as amended, is directed to a method of cooling a target tissue region inside a body. The method comprises restricting normal blood flow to the tissue region so that only a desired amount of blood is provided to the tissue region. The method also comprises providing cool fluid to mix with the blood provided to the tissue region so as to cool the tissue region below normal body temperature and to maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target temperature range that is one to nine degrees Celsius below normal body temperature.

Harrison does not disclose all of the limitations of Applicants' independent claim 18, as amended. For example, Harrison does not disclose, as required by claim 18 as amended, a method in which cool fluid is provided to mix with blood also provided to a tissue region so as to cool the tissue region below normal body temperature and to maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target temperature range that is one to nine degrees Celsius below normal body temperature.

Harrison's disclosure at page 6, paragraph 0063, which the Examiner also cites in support of his rejection, also does not disclose the method of claim 18 as amended. In this paragraph,

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 14 of 16

Attorney's Docket No.: 10527-522001 / 03-257

Harrison simply discloses replacing the cooled saline solution described previously in Harrison with "blood, a blood substitute, or a mixture of both." While not stated explicitly in this paragraph, it is clear from the context of Harrison that the replacement blood, blood substitute, or mixture would, like the saline, also be cooled, and provided from outside the body along with the blood substitute. As such, there is no disclosure in Harrison of mixing cooled fluid with a restricted amount of blood that is permitted to flow to a target tissue region.

In addition, as discussed previously and acknowledged by the Examiner, Harrison cannot preclude the patentability of claim 18 as obvious, because at the time of the invention both the present invention and Harrison were subject to assignment to the same assignee. 35 U.S.C. 103(c).

Accordingly, independent claim 18 is patentable in view of Harrison. Accordingly, Applicants ask that the Examiner remove his rejection of independent claim 18, as well as dependent claims 19-20 and 24-25.

#### **Claim Rejections – 35 U.S.C. § 103**

The Office Action rejected claims 8-10 and 21-23 under 35 U.S.C. § 103(a) as being obvious over Lewis. Independent claim 1, as discussed previously, is patentable over Lewis, and thus claims 8-10 which depend from claim 1 similarly are patentable over Lewis. Independent claim 18 is patentable over Lewis (indeed, claim 18 was not rejected based on Lewis), and thus claims 21-23 are patentable over Lewis.

Accordingly, Applicants ask that the Examiner remove the obviousness rejections of claims 8-10 and 21-23.

#### **Double Patenting**

The Office Action provisionally rejected claims 1-25 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of co-pending Application Nos. 11/356,481 and 11/357,558 (which are divisional applications claiming priority to the present application). Applicants note that the divisional applications were filed in response to a restriction requirement

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 15 of 16

Attorney's Docket No.: 10527-522001 / 03-257

being issued in the present case. In addition, Applicants in both cases have canceled claims 1-25 in a preliminary amendment.

Accordingly, Applicants ask that the Examiner remove the provisional rejection of claims 1-25 for double patenting.

### Conclusion

Applicants submit that all pending claims 1-25 are in condition for allowance, and ask that the Examiner issue a notice of allowance.

Applicants also note that a Supplemental Information Disclosure Statement (IDS) was filed on July 14, 2006, after mailing of the last Action, and request consideration of the references cited in this Supplemental IDS. For the Examiner's convenience, a copy of the PTO-1449 form filed July 14, 2006 is attached hereto. In addition, copies of the listed references can be resubmitted upon request.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicant : Martin Willard et al.  
Serial No. : 10/715,636  
Filed : November 18, 2003  
Page : 16 of 16


Attorney's Docket No.: 10527-522001 / 03-257

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Respectfully submitted,

Date: 10/6/06

  
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